DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 11, 2015

BIO-RAD LABORATORIES
SUZANNE PARSONS
REGULATORY AFFAIRS SUPERVISOR
9500 JERONIMO ROAD
IRVINE CA 92618-2017

Re: K150300
Trade/Device Name: Liquichek Cardiac Markers Plus Control LT
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJY
Dated: January 26, 2015
Received: February 6, 2015

Dear Suzanne Parsons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150300

Device Name
Liquichek Cardiac Marker Plus Control LT

Indications for Use *(Describe)*

Liquichek Cardiac Markers Plus Control LT is intended for use as a quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.

The following analytes are listed in the package insert:
B-type Natriuretic Peptide (BNP)
CK-MB Isoenzyme
C-Reactive Protein (CRP)
Creatine Kinase (CK)
D-dimer
Digitoxin
Homocysteine
Myeloperoxidase (MPO)
Myoglobin
N-terminal pro-Brain Natriuretic Peptide (NT-proBNP)
Troponin I
Troponin T

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Liquichek Cardiac Markers Plus Control LT

1.0 Submitter

Bio-Rad Laboratories
9500 Jeronimo Road,
Irvine, California 92618-2017
Telephone: (949) 598-1200
Fax: (949) 598-1557

Contact Person

Suzanne Parsons
RA Supervisor
Telephone: (949) 598-1467

Date of Summary Preparation

December 10, 2015

2.0 Device Identification

Product Trade Name:	Liquichek Cardiac Markers Plus Control LT
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classifications:	Class I, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

3.0 Device to Which Substantial Equivalence is Claimed

Liquichek Cardiac Markers Plus Control LT
Bio-Rad Laboratories
Predicate 510(k) Number: K050537

4.0 Description of Device

Liquichek Cardiac Markers Plus Control LT is prepared from human serum with added constituents of human and animal origin, stabilizers and preservatives. This product is provided in liquid form for convenience.

Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV) and antibody to HIV-1/HIV-2.

5.0 Value Assignment

The mean values and the corresponding ±3SD ranges printed in this insert were derived from replicate analyses and are specific for each lot of product. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of control. Individual laboratory means should fall within the corresponding acceptable range; however, laboratory means may vary from the listed values during the life of this control. Variations over time and between laboratories may be caused by differences in laboratory technique, instrumentation and reagents, or by manufacturer test method modifications.

It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

6.0 Intended Use

Liquichek Cardiac Markers Plus Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.

The following analytes are listed in the package insert:
B-type Natriuretic Peptide (BNP)
CK-MB Isoenzyme
C-Reactive Protein (CRP)
Creatine Kinase (CK)
D-dimer
Digitoxin
Homocysteine
Myeloperoxidase (MPO)
Myoglobin
N-terminal pro-Brain Natriuretic
Peptide (NT-proBNP)
Troponin I
Troponin T

7.0 Comparison of the new device with the Predicate Device

Liquichek Cardiac Markers Plus Control LT claims substantial equivalence to Liquichek Cardiac Markers Plus Control LT (*K050537*). Table 1 (below) contains comparison information of similarities and differences between the new and predicate device to which substantial equivalence is claimed.

Table 1: Comparison between the predicate and new Liquichek Cardiac Markers Plus Control LT		
Characteristics	Predicate Device	New Device
	Liquichek Cardiac Markers Plus Control LT (K050537)	Liquichek Cardiac Markers Plus Control LT
Similarities		
Product Name	Liquichek Cardiac Markers Plus Control LT	Liquichek Cardiac Markers Plus Control LT
Intended Use	Liquichek Cardiac Markers Plus Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.	Liquichek Cardiac Markers Plus Control LT is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert.
Base Matrix	Human Serum	Human Serum
Form	Liquid	Liquid
Thawed and Opened Stability	20 days at 2 to 8ºC Except: N-terminal pro-Brain Natriuretic Peptide (NT-proBNP): 15 days at 2 to 8°C Troponin I: 10 days at 2 to 8°C B-type Natriuretic Peptide (BNP): 8 days at 2 to 8°C Troponin T: 4 days at 2 to 8°C	20 days at 2 to 8ºC Except: N-terminal pro-Brain Natriuretic Peptide (NT-proBNP): 15 days at 2 to 8°C Troponin I: 10 days at 2 to 8°C B-type Natriuretic Peptide (BNP): 8 days at 2 to 8°C Troponin T: 4 days at 2 to 8°C
Frozen Aliquot Stability	30 days at -20 to -70°C	30 days at -20 to -70°C
Shelf life	at -20 to -70°C until expiration	at -20 to -70°C until expiration
Differences		
Analytes	*Contains* B-type Natriuretic Peptide (BNP) CK-MB Isoenzyme C-Reactive Protein (CRP) Creatine Kinase (CK) Digitoxin Homocysteine Myoglobin N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) Troponin I Troponin T Does not contain: D-dimer Myeloperoxidase (MPO)	*Contains* B-type Natriuretic Peptide (BNP) CK-MB Isoenzyme C-Reactive Protein (CRP) Creatine Kinase (CK) D-dimer Digitoxin Homocysteine Myeloperoxidase (MPO) Myoglobin N-terminal pro-Brain Natriuretic Peptide (NT-proBNP) Troponin I Troponin T

8.0 **Statement of Supporting Data**

Real time stability studies were performed to establish Thawed and Opened stability claims. Accelerated stability studies were performed for establishing the shelf life stability. The stabilities for Liquichek Cardiac Markers Plus Control LT are as follows:

Thawed and Opened Stability:	N-terminal pro-Brain Natriuretic Peptide (NT-proBNP): 15 days at 2 to 8°C Troponin I: 10 days at 2 to 8°C B-type Natriuretic Peptide (BNP): 8 days at 2 to 8°C Troponin T: 4 days at 2 to 8°C All other analytes: 20 days at 2 to 8°C
Frozen Aliquot Stability:	30 days at -20 to -70°C
Shelf Life Stability:	36 months at -20 to -70°C

9.0 **Conclusion**

Based on the performance characteristics indicated above, Liquichek Cardiac Markers Plus Control LT is substantially equivalent to the predicate device (K050537).

All supporting data is retained on file at Bio-Rad Laboratories.